510(k) Summary

JAN 1 5 2003

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Date of Preparation of this Summary:	December 5, 2002
Device Trade or Proprietary Name:	Rheumatoid Factor
Device Common/Usual Name or Classification Name:	Rheumatoid Factor
Classification Number/Class:	DHR, Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K024067

Test Description:

Rheumatoid Factor is an *in vitro* diagnostic assay for the quantitative determination of rheumatoid factor in human serum. The RF assay is a latex enhanced immunoturbidimetric assay that involves an antigen-antibody reaction between the rheumatoid factor in the sample and the denatured human IgG, which has been adsorbed to latex particles. The resulting agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of RF in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

Substantial Equivalence:

The Rheumatoid Factor assay is substantially equivalent to the Roche Diagnostics Corp. Tina-quant RF II assay (K002609) on the Hitachi® 717 Analyzer.

Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are *in vitro* immunoassays.
- Both assays can be used for the quantitative determination of rheumatoid factor.
- Both assays yield similar clinical results.
- Both assays are based on the measurement of the agglutination following antigen-antibody reaction.
- Human serum is a suitable specimen for both assays.

Differences:

- There is a difference between the assay range.
- Suitable specimens for the Roche Diagnostics Corp. Tina-quant RF II assay include plasma specimens.

Intended Use:

The Rheumatoid Factor assay is used for the quantitation of rheumatoid factor in human serum.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® System. The Rheumatoid Factor assay method comparison yielded acceptable correlation with the Roche Diagnostics Corp. Tina-quant RF II assay on the Hitachi 717 Analyzer. On the AEROSET System, the correlation coefficient = 0.996, slope = 1.14, and the Y-intercept = 2.14 IU/mL. Precision studies were conducted using the Rheumatoid Factor assay. Within-run, between-run, and between-day studies were performed using three levels of control material. On the AEROSET System, the total %CV for Level 1 ranged from 4.6% to 7.5%, Level 2 ranged from 3.6% to 4.3%, and Level 3 ranged from 1.2% to 2.0%. The Rheumatoid Factor assay range is 4.8 to 200.0 IU/mL. The limit of quantitation (sensitivity) of the Rheumatoid Factor assay is 7.71 IU/mL on the AEROSET System. These data demonstrate that the performance of the Rheumatoid Factor assay is substantially equivalent to the performance of the Roche Diagnostics Corp. Tina-quant RF II assay on the Hitachi 717 Analyzer.

Conclusion:

The Rheumatoid Factor assay is substantially equivalent to the Roche Diagnostics Corp. Tina-quant RF II assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Linda Morris
Senior Regulatory Specialist
ADD Regulatory Affairs
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Re: k024067
Trade/Device Name: Rheumatoid Factor
Regulation Number: 21 CFR § 866.5775
Regulation Name: System, Test, Rheumatoid Factor
Regulatory Class: II
Product Code: DHR
Dated: December 5, 2002
Received: December 10, 2002

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K024067

Device Name: Rheumatoid Factor

Indications For Use:

The Rheumatoid Factor assay is used for the quantitation of rheumatoid factor in human serum. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

A. Reeves for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024067